



August 6, 2021

Ms. Elise Barringer
Designated Federal Official (DFO)
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-1764-N

Dear Ms. Barringer:

The Alliance of Wound Care Stakeholders is a nonprofit multidisciplinary trade association representing physician specialty societies, clinical and patient associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Our members possess expert knowledge in complex chronic wounds, and in wound care research. These clinicians treat patients with wounds in all settings – including the hospital outpatient arena. A list of our members can be found on our website: (www.woundcarestakeholders.org).

The Alliance respectfully requests that the Panel recommend to CMS that:

- CMS assign the existing CPT add-on codes (15272 and 15276; 15274 and 15278) to an appropriate APC group allowing for payment and issue an exception for the payment of CTP add-on codes.
- Assign APCs for the same size wound regardless of anatomical location on the body.

Our recommendations stem from the following two patient access issues which are related to the prohibitive cost that Provider Based Departments (PBDs) incur if they provide skin substitutes or Cellular and/or Tissue Based Products for Skin Wounds (CTPs) to patients with larger medically necessary wounds/ulcers.

Assignment of Add-On Codes to Appropriate APC

The first barrier to access relates to the add-on codes. When the payment for CTPs were packaged into the payment for the application, the add-on codes were also packaged. Because the add-on codes represent wounds and ulcers that require the purchase of additional product, patients with wounds larger than 25 sq. cm up to 99 sq. cm and also those greater than 100 sq. cm, are not being offered medically necessary CTPs in the Provider Based Departments (PBDs). The reason for this is that the add-on codes that are packaged into the OPSS bundled rates are not adequate to allow the PBDs to purchase the sizes of CTPs necessary to apply to all wound sizes. In fact, none of the add-on codes have been available for additional payment.

To remedy this issue, the Alliance urges the Panel to recommend that CMS issue an exception for the payment of CTP application add-on codes. The allowance of payment for the add-on codes is an easy remedy for CMS to implement and there has been precedent set in CMS providing these types of exceptions, (i.e. chemotherapy).

Additionally, the Alliance recommends that APC 5053, 5054 and 5055 be retained but additional APCs should be added to appropriately address the costs to purchase the appropriate amount of product for wounds 1-25 sq. cm., 26-50 sq. cm., 51-75 sq. cm., 76-99 sq. cm., and each additional 100 sq. cm. Again, currently, the CPT codes are assigned to APCs based on the wound size - smaller wounds (under 25 sq. cm) or larger size wounds (over 100 sq. cm). The current system makes CTPs for patients with wounds that are in between 25 sq. cm and 100 sq. cm as well as those over 100 sq. cm. cost-prohibitive since facilities are not getting reimbursed for the extra product that is being utilized to treat the patient's medically necessary wounds.

In order to appropriately pay PBDs now for the various sizes of products required for the wounds and most importantly, so that patients with larger wounds can gain medically necessary access to CTPs, each base code for the application of the products must track to separate APC groups and each add-on code must also track to separate APC groups. There must be payment for the add-on codes.

As such, the Alliance specifically requests that the Panel recommend that CMS assign the existing CPT add-on codes (15272 and 15276; 15274 and 15278) to appropriate APCs allowing for payment and recommend to CMS that they issue an exception for the payment of CTP add-on codes.

Assignment of APC for the Same Size Wound Regardless of Anatomical Location

The second access issue relates to where a wound/ulcer is located and what APC CMS has assigned. The APC for the same size should be the same whether the ulcer is located on the leg or foot, since the same resources and product are utilized. However, that is not how CMS has assigned the APCs. This example illustrates why this is problematic:

Both Patient A and Patient B have leg ulcers. Patient A has a 75 sq. cm wound/ulcer and Patient B has a wound/ulcer measuring 125 sq. cm. The CPT code 15271 is appropriately assigned to APC 5054, for the patient with the 75 sq. cm wound and 15273 is appropriately assigned to APC 5055 for the patient with the 125 sq. cm wound as the PBD has to purchase more product for the patient with the 125 sq. cm ulcer/wound.

However, if the application of CPTs were both provided to Patient A and Patient B with the same size wound/ulcer, but in this case, the CTP application was on their foot instead of the leg, the CPT code for Patient A would be 15275 and the application code for Patient B would be 15277. Both would be assigned to the same APC-5054. However, the PBD utilized 50 sq. cm more product when billing application code 15277 for Patient B. They should have been assigned 5055. The PBD purchased the same amount of product – whether the ulcer/wound was located on the patient's leg or their foot and as such, 15277 and 15273 should both be assigned to APC 5055 to provide patients with access to medically necessary CTPs.

The Alliance recommends that the Panel urge CMS to assign APCs regardless of anatomic location so that 15273 and 15277 are assigned to APC 5055 while 15271 and 15275 continue to be assigned to APC 5054.

Finally, for the past several years CMS has been placing alternative payment methodology proposals for CTPs in the hospital outpatient proposed rules in order to move away from the high/ low cost tiered system currently in place. This year, there had been no recommendation from the Agency in this proposed rule. We have been working with the Agency for many years on this issue and most recently sent them a March 23, 2021 letter and a follow up conference call. We believe that a new methodology is long past due and the Alliance is willing to work with CMS to refine its methodology for 2023.

The Alliance appreciates consideration of the Panel requesting CMS to move forward with our recommendations.

Sincerely

A handwritten signature in black ink that reads "Marcia Nusgart R.Ph." in a cursive script.

Marcia Nusgart R.Ph.
Executive Director

PATIENT ACCESS BARRIERS – COST

Patient Scenario	Appropriate Codes	Average Per Application Product Cost for Ulcer Size	OPPS Packaged Payment	Avg. Per Application Potential Loss to PBD
75 sq. cm foot ulcer	15275	\$7256.12	APC 5054 \$1759.21	\$5540.76
	15276		Needs an APC	
125 sq. cm foot ulcer	15277	\$10267.82	APC 5054 \$1759.21	\$8552.46
	15278		Needs an APC	
75 sq. cm leg ulcer	15271	\$7256.12	APC 5054 \$1759.21	\$5540.76
	15272		Needs an APC	
125 sq. cm leg ulcer	15273	\$10267.82	APC 5055 \$3613.14	\$6745.67

* Data from CMS's Part B Pricing Data File

